



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Mifepristone and Analogues to Treat Hypercortisolism-related Insulin Resistance Disorders

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Institute of Diabetes and Digestive and Kidney Diseases, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the invention embodied in the patents and patent applications listed in the Supplementary Information section of this notice to Nulyn Science (“Nulyn”), a company located in Paris, France.

DATES: Only written comments and/or applications for a license which are received by the National Institute of Diabetes and Digestive and Kidney Diseases’ Technology Advancement Office on or before [INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Inquiries and comments relating to the contemplated Exclusive Patent License should be directed to: Betty B. Tong, Ph.D., Senior Licensing and Patenting Manager, NIDDK Technology Advancement Office, Telephone: (301)-451-7836;
E-mail: tongb@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

1. Australian Patent Application No. 2020239920 filed March 9, 2020, entitled “Method for Improving Insulin Sensitivity” [HHS Reference No. E-081-2019-0-AU-01];
2. South Korean Patent Application No. 10-2021-7033113 filed March 9, 2020, entitled

- “Method for Improving Insulin Sensitivity” [HHS Reference No. E-81-2019-0-KR-01];
3. New Zealand Patent Application No. 781109 filed October 7, 2020, entitled “Method for Improving Insulin Sensitivity” [HHS Reference No. E-081-2019-0-NZ-01];
 4. United States Patent Application No. 17/438, 580 filed September 13, 2021, entitled “Method for Improving Insulin Sensitivity” [HHS Reference No. E-081-2019-0-US-02];
 5. United States Patent Application No. 18/831,326 filed November 19, 2024, entitled “Method for Improving Insulin Sensitivity” [HHS Reference No. E-081-2019-0-US-03];
 6. European Patent 3941460, issued October 15, 2025, entitled “Method for Improving Insulin Sensitivity” [HHS Reference No. E-81-2019-0-EP-01].

The patent rights in the invention have been assigned to the Government of the United States of America.

The prospective exclusive license territory may be “worldwide”, and the field of use may be limited to the following:

“Commercial development of mifepristone and analogues for treatment of hypercortisolism-related insulin resistance disorders in humans”

The subject technology describes a method of treating or ameliorating insulin sensitivity disorders using glucocorticoid receptor antagonist (GRA), like mifepristone, to block the metabolic side effects of cortisol, which is a key driver of hepatic and adipose insulin resistance. The invention relates to a specific dosing approach that restricts dosage to avoid over-activating the hypothalamic-pituitary-adrenal (HPA) axis and ensure cortisol safety levels.

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Institute of Diabetes and Digestive and Kidney Diseases receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

Complete applications for a license that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive patent license. In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain confidential business information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: August 28, 2026

Charles D. Niebylski,

Director,

Technology Advancement Office,

National Institute of Diabetes and Digestive and Kidney Diseases.

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